GIRARD SHARP LLP
Dena C. Sharp (State Bar No. 245869)
Adam E. Polk (State Bar No. 273000)
Nina R. Gliozzo (State Bar No. 333569)
Patrick T. Johnson (State Bar No. 329580)
601 California Street, Suite 1400
San Francisco, CA 94108
Telephone: (415) 981-4800
Email: dsharp@girardsharp.com
Email: apolk@girardsharp.com
Email: ngliozzo@girardsharp.com
Email: pjohnson@girardsharp.com

Counsel for Plaintiffs and the Proposed Class

[Additional Counsel on Signature Page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

T.U. and V.W., individually and on behalf of all others similarly situated,

Plaintiffs,

v.

COOPERSURGICAL, INC.,

Defendant.

Case No. 4:24-cv-01261-JST

SECOND AMENDED CLASS ACTION COMPLAINT

1. Strict Products Liability – Manufacturing Defect
2. Strict Products Liability – Design Defect
3. Strict Products Liability – Failure to Warn
4. Negligent Failure to Recall
5. Negligence and/or Gross Negligence
6. Trespass to Chattels
7. Unjust Enrichment

DEMAND FOR JURY TRIAL

INTRODUCTION

1. This is a class action on behalf of individuals who sought to build their families through in vitro fertilization ("IVF"), but their developing embryos were damaged or destroyed because they were exposed to defective culture media products made by Defendant, Coopersurgical, Inc. ("CooperSurgical" or "Defendant").

2. CooperSurgical manufactured, marketed, and sold products to fertility clinics, including a culture media product designed to support the growth and development of embryos created through IVF. The culture media is a nutrient-rich liquid that surrounds a fertilized egg during the incubation period to help it develop into a viable embryo as part of the IVF process.

3. In December 2023, CooperSurgical recalled certain lots of its culture media products, which had been sold to hundreds of fertility clinics across the United States, based on evidence that they were defective and could actually harm and destroy embryos instead of helping them grow.

4. Plaintiffs T.U. and V.W. are a couple that sought fertility treatment at a fertility clinic in Northern California, undergoing the expensive and emotionally taxing process of IVF in the hopes of having children. To maximize their chances, Plaintiffs T.U. and V.W. secured donor eggs from a young, healthy donor. Their plan was to implant the healthy embryos in Plaintiff T.U.'s uterus so that she could experience carrying their child to term.

5. Unfortunately, Plaintiffs' fertility clinic used Defendant's defective culture media products. Using V.W.'s sperm, Plaintiffs' clinic successfully fertilized six donor eggs and placed them in CooperSurgical's culture media, on the expectation that it would help the fertilized eggs develop into viable embryos.

6. Six of T.U. and V.W.'s eggs were fertilized, all but one of the resulting embryos stopped growing before reaching viability and were destroyed as a result of Defendant's defective culture media. The remaining embryo was genetically tested, but the results indicated that it was genetically abnormal and thus could not be used to start a pregnancy.

7. Because of Defendant's manufacturing, marketing, promoting, distributing, and/or selling its defective culture media, Plaintiffs lost invaluable, irreplaceable property—embryos that could have

grown into their children—and were emotionally, physically, and psychologically damaged. Plaintiffs bring this action to hold Defendant accountable for its conduct.

8. Plaintiffs, on behalf of themselves and all other similarly situated individuals, seek damages, equitable relief, and other remedies from Defendant.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because (a) Plaintiffs are citizens of a state different from CooperSurgical, (b) the amount in controversy exceeds $5,000,000, excluding interest and costs, (c) the proposed class consists of more than 100 individuals, and (d) none of the exceptions under the subsection applies to this action.

10. This Court has personal jurisdiction over Defendant. It conducts substantial business in this District and has intentionally availed itself of the laws and markets of this District, and Defendant resides in this district. A significant portion of the acts and omissions complained of occurred in the District.

11. Venue is proper in this District under 28 U.S.C. § 1391 because Defendant resides in this district and a substantial part of the events or omissions giving rise to this action occurred in this district.

INTRADISTRICT ASSIGNMENT

12. Assignment to the San Francisco or Oakland Division is proper under Local Rules 3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in Contra Costa county.

PARTIES

13. Plaintiff T.U. is a citizen and resident of San Jose, California.

14. Plaintiff V.W. is a citizen and resident of San Jose, California.

15. Given the sensitive nature of their claims, Plaintiffs are using randomized initials to protect their privacy. The Court entered an Order on the parties' stipulation agreeing to certain procedures to proceed using pseudonyms. *See* Dkt. 39.

16. Defendant CooperSurgical, Inc. is a Delaware corporation with its principal place of business in Trumbull, Connecticut.

FACTUAL ALLEGATIONS

A. In Vitro Fertilization Procedure

17. IVF has become an established means of allowing individuals and couples the opportunity to become pregnant using their biological material. IVF provides the flexibility to begin a family when it makes sense for individuals and couples personally and professionally. IVF is also a way for those suffering from infertility to start their families, using their own biological material.

18. An IVF cycle typically includes the following steps or procedures: (1) the patient takes medications, including regular injections of hormones, to grow multiple eggs; (2) the clinic retrieves the patient's eggs from the ovary or ovaries; (3) the eggs are inseminated with sperm; (4) the clinic cultures any resulting fertilized eggs, fostering their development into embryos, including with the use of culture media; (5) one or more embryo(s) are placed ("transferred") into the patient's uterus; and (6) the patient takes additional hormones to support of the uterine lining to permit and sustain pregnancy.

19. In certain cases, additional procedures may be employed, including (1) intracytoplasmic sperm injection ("ICSI") to increase the chance for fertilization; (2) assisted hatching of embryos to potentially increase the chance of embryo attachment ("implantation"); and (3) cryopreservation (freezing) of eggs or embryos.

20. The success of IVF largely depends on growing multiple eggs at once and then retrieving the eggs (egg retrieval process). To achieve this goal, patients undergo a strict regimen of injections with hormones and other medicines. These injections can cause a plethora of known side effects, including but not limited to bruising, redness, swelling, or discomfort at the injection site, bloating, weight gain, water retention, bone loss, fatigue, headaches, muscle aches, abdominal pain, breast tenderness, vaginal yeast infections, vaginal dryness, bone loss, hot flashes, mood swings, depression, nausea, vomiting, diarrhea, clots in blood vessels and strokes. Women injected with these pharmaceuticals also run the risk of a potentially fatal allergic reaction to the drugs. And up to 2% of women will develop Ovarian Hyperstimulation Syndrome ("OHSS"), a life-threatening condition that can cause increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, increased concentration of red blood cells, kidney and liver problems, blood clots, kidney failure, and death.

21. IVF requires multiple doctor visits involving routine blood tests and invasive transvaginal ultrasound examinations, which are often scheduled with very little advanced warning. IVF also places restrictions on diet, work, and travel.

22. The egg retrieval process itself involves surgery conducted under anesthesia, where the eggs are extracted with a large needle inserted through the vaginal wall. Risks of the egg retrieval procedure include infection, bleeding, trauma to intra-abdominal organs, allergic reactions, low blood pressure, nausea, vomiting, and in rare cases, death. After the retrieval procedure, a patient often experiences residual pain for about a week and may need bedrest for several days.

23. Another potential risk is that the procedure will fail to obtain any eggs, or the eggs may be abnormal or of poor quality and otherwise fail to produce a viable pregnancy.

24. Based on their age and medical status, women may undergo multiple rounds of retrievals to obtain enough eggs or embryos to achieve their reproductive goals. This process can take months or even years. On average, women and couples spend $40,000-$60,000 out of pocket for these services.

25. If and when viable eggs are retrieved, IVF and embryo culture occurs. Sperm and eggs are placed together in specialized conditions (culture media, controlled temperature, humidity, and light) to achieve fertilization. Sperm and eggs are submerged in culture media, which is a nutrient-rich liquid designed to promote the growth and development of a fertilized egg into a viable embryo by replicating the natural environment and fluids in a woman's reproductive system. When they develop successfully, embryos grow and reach certain milestones for viability over the course of several days following insemination.

26. After the egg retrieval process, IVF patients can either receive a fresh embryo transfer or a frozen embryo transfer. A fresh transfer occurs after a few days of embryo development. Embryos are selected for transfer and are placed in the uterine cavity with a tube. By contrast, a frozen transfer involves cryogenically freezing the embryo, then after a period of time, unthawing the embryo and placing it in the patient's uterus. Frozen transfers allow a patient to elect to genetically screen the embryos to determine if any suffer from genetic abnormalities making them unsuitable for transfer. If multiple viable embryos are created in an IVF cycle, patients can opt to do a fresh transfer of one or more embryos and freeze others for later transfer attempts. Excess embryos of sufficient quality that are not transferred

can be frozen. So long as they are properly stored, frozen embryos can remain viable and be transferred years after they are retrieved.

B. The Loss of Eggs and Embryos Has Severe Consequences

27. People who engage in fertility services make large monetary and emotional investments. They endure painful and invasive procedures, financial stress, and the strain the process puts on their mental health and relationships with others, all in the hopes that one day they will be able to have a child.

28. In addition to the physical burdens of IVF, the process is also emotionally grueling. The success or failure of IVF, including egg retrieval and embryo storage, has substantial emotional and psychological ramifications for those seeking to become parents.

29. For many, the IVF process represents their last hope for having children. Many women experience and express strong feelings of anxiety, failure, hopelessness, and disappointment during this process. The IVF process can affect a patient and her spouse or partner medically, financially, socially, emotionally, and psychologically. Feelings of anxiety, depression, isolation, and helplessness are not uncommon in patients undergoing IVF. Losing eggs and embryos provokes fear, devastation, and despair. Many people experience grief and anguish when fertility treatment does not result in pregnancy or when they lose fertility choices.

30. As discussed above, women take drug and hormone cocktails and injections over several weeks to stabilize the uterine lining, stimulate ovaries into producing follicles, and stop these ovary follicles from releasing eggs. A woman may be subjected to multiple injections each day, resulting in bruising, swelling, and discomfort. The drug and hormone therapy may also trigger other side effects, such as tiredness, nausea, headaches, and blood clots, as well as negative emotions. The process can limit travel and other activities, entails numerous doctor visits, and often requires time off from work. The retrieval procedure itself requires anesthesia, as well as insertion of a thick needle through the vaginal wall to drain the ovary follicles of their fluid. After the procedure, a woman often experiences residual pain for about a week and may need bed rest for several days. Some women suffer significant side effects, such as ovarian hyperstimulation syndrome, requiring hospitalization.

31. These invasive services are expensive. According to recent estimates, "a single IVF cycle—defined as ovarian stimulation, egg retrieval and embryo transfer—can range from $15,000 to

$30,000, depending on the center and the patient's individual medication needs."[1] Clients typically pay thousands of dollars for fertility drugs leading up to egg retrieval and may also spend hundreds of dollars on acupuncture and other services recommended to them to improve outcomes. Depending on age and health status, some women will undergo (and pay for) more than one IVF cycle, or if they freeze multiple embryos, will pay thousands of dollars for each transfer attempted with an existing embryo.

32. Defendant is aware of the lengths to which people go to obtain eggs and create embryos, how much they mean to patients, the patients' emotional (and financial) investment in the survival of the eggs and embryos, and the patients' expectations that great care will be taken to preserve and protect the eggs and embryos to avoid irreparable, devastating harm.

33. Eggs and embryos are precious. They offer the opportunity to fulfill one of the most fundamental human urges: to become a parent and create one's own family when the time is right. Eggs and embryos are also irreplaceable. The most determinative factor in IVF success is the woman's age at the time her eggs were extracted. At some point, usually around her mid-40s, a woman can no longer produce viable eggs. When preserved eggs or embryos are damaged or compromised, it may be impossible for clients to build their family as they had planned.

C. Defendant Manufactures and Sells Culture Media for Growing Embryos

34. CooperSurgical describes itself as "a leading fertility and women's health company dedicated to putting time on the side of women, babies, and families at the healthcare moments that matter most in life."[2]

35. Defendant has positioned itself as a leader in the reproductive health and infertility treatment fields.

36. Specifically describing its role in the fertility space, CooperSurgical's website promises that "[w]hen you partner with us you become part of a truly global network of scientific leaders, embryologists and clinical training experts, ready to support you with highly specialized solutions, both for individual clinics and across large organizations. By providing you with optimal products, service and

[1] https://www.forbes.com/health/womens-health/how-much-does-ivf-cost/.

[2] https://www.coopersurgical.com/about-us.

training our aim is to offer you the best possible support to drive the efficiency of your clinic – and achieve the best possible results."[3]

37. CooperSurgical advertises its embryo culture media product, called Global Media, as a "Single-step medium for uninterrupted embryo culture," noting that it is "[d]esigned for D1-5 embryo culture and transfer," "[c]ontains energy substrates and essential amino acids to support embryo growth and development," and "[t]he performance of global has been demonstrated through 15 years of use and 500 independent publications using global medium."[4]

38. Culture media for embryo development is designed to meet the nutritional needs of developing embryos by providing necessary sources of energy, nutrients, and pH levels based on the specific developmental stage of the embryo. Embryo culture media is typically comprised of multiple ingredients including carbohydrates, amino acids, vitamins, magnesium, and growth factors. The nutrients in the media are crucial to an embryo's successful growth.

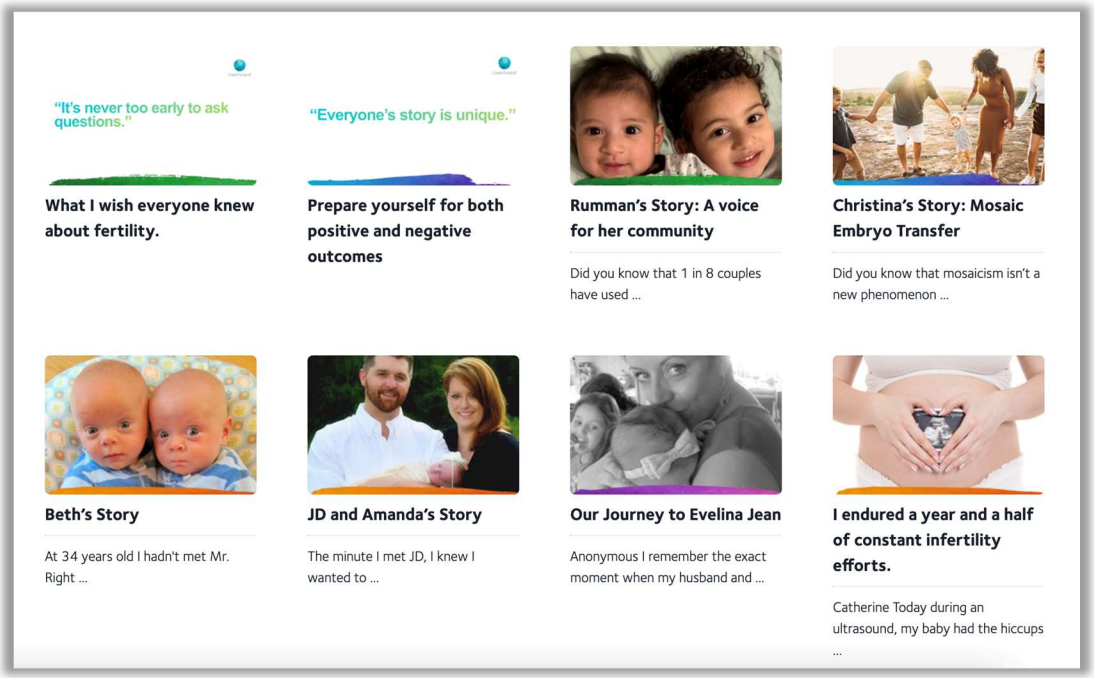
39. Magnesium is required for embryonic development and is a key element to repair mutations during cell division. Insufficient magnesium levels in embryo culture media can cause embryo growth to arrest and inhibit DNA repair.

40. Defendant is aware of the lengths families engaged in IVF go to extract eggs and create embryos, their emotional and financial investment in the survival of their embryos, and their expectations that their embryos will be handled with care to avoid irreparable, devastating harm. CooperSurgical's website includes patient testimonials from families struggling with infertility, as shown in the screenshot from the website below, including articles titled "Christina's Story: Mosaic Embryo Transfer," "What I wish everyone knew about fertility," and "I endured a year and a half of constant infertility efforts."[5]

[3] https://fertility.coopersurgical.com/about-us/.

[4] https://www.coopersurgical.com/product/global; *see also* https://fertility.coopersurgical.com/art_media/global/.

[5] https://www.coopersurgical.com/patients/patient-article-list?refinementList%5Blife_stage_name%5D%5B0%5D=I%20want%20kids.



41. Defendant recognizes that it engages in a peculiarly sensitive and emotional business by manufacturing and supplying IVF products used by families who face barriers to conceiving a healthy child.

42. CooperSurgical's fertility division is highly profitable. Its CEO acknowledged that CooperSurgical experienced twelve consecutive quarters of "double-digit" growth in its fertility division, generating $1.2 billion in revenue last year.[6]

D. Recall of Defendant's Embryo Culture Media

43. In a letter dated December 5, 2023, CooperSurgical issued an Urgent Recall Notice for certain lots of its Global Media culture product.[7] Global Media Lots number 231020-018741, 231020-018742, and 231020-018743 were recalled, with part numbers LGGG-100, LGGG-50, and LGGG-20.

44. The Recall Notice states "CooperSurgical has become aware of a sudden increase in complaints regarding the aforementioned lots of this product," acknowledged that the "risk to health is

[6] https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/.

[7] Exhibit A, CooperSurgical Recall Notice (December 5, 2023).

impaired embryo development prior to the blastocyst stage," and directed clinics who purchased the product to quarantine and return it.[8]

45. According to regulatory authorities, CooperSurgical issued the recalls because the recalled batches of the Global Media were deficient in magnesium.[9]

46. Defendant knew or should have known that magnesium is a critical component and essential element of embryo culture media, and that a lack of magnesium in the Global Media may result in the destruction or arrested development of human embryos.

47. Defendant nevertheless failed to adequately monitor its manufacturing systems and processes, and allowed for the production of embryo culture media without ensuring that sufficient amounts of magnesium was included.

48. Defendant did not properly test or inspect the impacted lots of Global Media until after receiving numerous complaints from fertility clinics that embryos cultured in Defendant's Global Media were dying at elevated rates.

49. The FDA posted a notice on its website regarding the recall in February 2024, estimating that 994 bottles of culture media were affected, 481 of which were purchased by clinics across the United States.[10]

50. A New York Times article on the recall reported that, according to Mitchel C. Schiewe, an embryologist and a laboratory director at California Fertility Partners, "each bottle holds enough liquid for multiple patients, though it's unclear how many bottles were opened before the December recall. If clinics used even half of the affected bottles, as many as 20,000 patients could have been affected."[11]

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[8] *Id.*

[9] https://www.laweekly.com/coopersurgical-recalls-faulty-i-v-f-liquid-destroying-embryos/ ("Regulatory authorities have revealed that CooperSurgical issued recalls for several batches of its I.V.F. product due to a crucial nutrient, Magnesium, being deficient").

[10] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205122 (noting distribution of the recall product in the United States "Nationwide including in the states of AL, AZ, CA, CO, FL, GA, IL, IN, IA, KS, KY, LA, MD, MA, MI, MO, NV, NJ, NM, NY, NC, OH, OK, OR, PA, RI, TN, TX, UT, VT, VA, WA, WV").

[11] https://www.nytimes.com/2024/02/15/health/cooper-surgical-ivf-embryos-lawsuits.html.

E. Plaintiffs were harmed by Defendant's Defective Culture Media

51. T.U. and V.W. are a couple who sought help growing their family through IVF treatment.

52. T.U. and V.W. engaged in IVF treatment at Zouves Fertility Center in Foster City, California. The IVF process produced six fertilized eggs that were to be developed into viable embryos.

53. On or around December 8, 2023, using V.W.'s sperm and donor eggs, Plaintiffs' fertility clinic fertilized six of the donor eggs and placed them in Defendant's culture media.

54. Each of the six eggs was successfully fertilized, but all but one of T.U. and V.W.'s developing embryos were destroyed due to Defendant's defective culture media. The remaining embryo developed to blastocyst, but was later determined through genetic testing to be chromosomally abnormal and thus unusable.

55. T.U. and V.W. were notified on or around February 15, 2024, via email, that all of their embryos were exposed to the defective culture media, which was subject to a recall. Plaintiffs' fertility clinic advised them as follows:

> We have been informed by CooperSurgical, the supplier of the culture medium LifeGlobal® global® media that was used in your cycle performed at ZFC in December 2023, that your cycle may have been negatively affected by a quality control issue with this batch of media. This quality control issue could have resulted in fewer embryos than you would otherwise have made embryo development [sic].

56. The embryos Plaintiffs lost are irreplaceable. Plaintiffs T.U. and V.W. are both older now. As a result, even if Plaintiffs are able to afford to create additional embryos—an emotionally taxing and financially costly procedure that is by no means guaranteed to succeed—those embryos made with older sperm may not have as high of a chance of successfully developing into a healthy child or children, and Plaintiff T.U. faces heightened risks of possible health complications from carrying a child to term.

CLASS ACTION ALLEGATIONS

57. Plaintiffs bring this action, on behalf of themselves and all others similarly situated, as a class action pursuant to Federal Rule of Civil Procedure 23(b)(1), 23(b)(2), 23(b)(3), and where applicable, 23(c)(4), on behalf of the following Class:

> All individuals in the United States whose eggs and/or embryos were exposed to Recalled Lots of Defendant's Global Media product (Global Media Lots number 231020-018741, 231020-018742, and 231020-018743).

Plaintiffs reserve the right to modify, expand, or narrow the proposed Class definition, including based on discovery and further investigation.

58. Excluded from the class are Defendant, its affiliates and subsidiaries, and its officers, directors, partners, employees, and agents; class counsel, their immediate family members, and employees of their firms; counsel for Defendant, their immediate family members, and employees of their firms; and judicial officers assigned to this case and their staffs and immediate family members.

59. Numerosity. The members of the class are so numerous that their individual joinder is impracticable. There are at least hundreds of class members, whose names and addresses can be discerned from Defendant's records and the records of the ferility clinics who used the Recalled Lots of Defendant's Global Media product.

60. Existence and Predominance of Common Questions of Fact and Law. This action involves common questions of law and fact that predominate over any questions affecting individual class members, including, without limitation:

a. Whether the Recalled Lots of Defendant's embryo culture media were defectively manufactured;

b. Whether the Recalled Lots of Defendant's embryo culture media were defectively designed;

c. Whether Defendant is strictly liable for failing to recall the Recalled Lots of embryo culture media sooner;

d. Whether Defendant negligently failed to recall the Recalled Lots of embryo culture media sooner;

e. Whether any defect in the Recalled Lots of Defendant's embryo culture media resulted from Defendant's negligence or other wrongful conduct;

f. Whether Defendant failed to take adequate and reasonable measures to ensure that its embryo culture media would be safely made;

g. Whether Defendant owed a duty to Plaintiffs and class members to protect the developing embryos entrusted to Defendant's care through the use of its embryo culture media product;

h. Whether Defendant breached its duties to protect the developing embryos that Plaintiff and class members entrusted to its care through the use of its embryo culture media product;

i. Whether Defendant trespassed the chattels of Plaintiffs and class members by damaging their personal property—developing embryos—through exposure to Defendant's defective culture media;

j. Whether Defendant was unjustly enriched through its conduct; and

k. Whether Plaintiff and class members suffered harm as a result of Defendant's violations and, if so, the appropriate measure of damages, restitution, or rescission.

61. Typicality. Plaintiffs' claims are typical of the other class members' claims because Plaintiffs and class members were subjected to the same wrongful conduct and damaged in the same way by having their developing embryos damaged or destroyed through exposure to Defendant's defective culture media.

62. Adequacy of Representation. Plaintiffs are adequate class representatives. Their interests do not conflict with the interests of the other class members they seek to represent. They have retained counsel competent and experienced in complex class action litigation, and they intend to prosecute this action vigorously. Plaintiffs and their counsel will fairly and adequately pursue and protect the interests of the class.

63. Superiority. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by Plaintiffs and the other class members are relatively small compared to the burden and expense that would be required to individually litigate these claims. As a result, it would be impracticable for many class members to seek redress individually. Individualized litigation would also create a potential for inconsistent or contradictory judgments and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

64. Class certification is also appropriate under Rules 23(b)(1), (b)(2), and/or (c)(4) because:

- The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications establishing incompatible standards of conduct for Defendant.
- The prosecution of separate actions by individual Class members would create a risk of adjudications that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or would substantially impair or impede their ability to protect their interests.
- Defendant has acted or refused to act on grounds generally applicable to the Class, making injunctive and corresponding declarative relief appropriate with respect to the Class as a whole; and
- The claims of Class members are comprised of common issues whose resolution in a class trial would materially advance this litigation.

FIRST CAUSE OF ACTION

Strict Products Liability – Manufacturing Defect

65. Plaintiffs incorporate the above and below allegations by reference.

66. Defendant is strictly liable to Plaintiffs and class members for harm caused by manufacturing defects in its culture media under California products liability law.

67. Defendant manufactured, tested, supplied, distributed, and/or sold the culture media used on Plaintiffs' and class members' embryos.

68. Defendant's culture media contained at least one manufacturing defect when it left Defendant's possession. The culture media was defective in that it differed from Defendant's intended result, did not conform to Defendant's design or specifications, and/or differed from other typical units of the same product. In particular, among other possible defects, the media lacked a sufficient level of magnesium, such that it destroyed or hindered the development of human embryos.

69. Defendant's culture media was used as intended when it came into contact with Plaintiffs' and class members' embryos.

70. The culture media's defect was a substantial factor in causing Plaintiffs' and class members' damages, including economic loss, serious emotional distress, and other harm in an amount to be determined at trial.

SECOND CAUSE OF ACTION

Strict Products Liability – Design Defect

71. Plaintiffs incorporate the above and below allegations by reference.

72. In addition or as an alternative to the first cause of action, Defendant is strictly liable to Plaintiffs and class members for harm caused by design defects in the culture media under California products liability law.

73. Defendant manufactured, tested, supplied, distributed, and/or sold the culture media, which was defectively designed under the consumer expectations test and/or the risk-benefit test.

Consumer Expectations Test

74. Defendant's culture media did not perform as safely as ordinary users of culuture media expect when used or misused in an intended or reasonably foreseeable way.

75. Defendant's culture media caused Plaintiffs' and class members' embryos to stop developing and prevented them from reaching viability. Ordinary users do not expect culture media to prevent embryo development.

76. Defendant's culture media's failure to perform safely was a substantial factor in causing Plaintiffs' and class members' damages, including economic loss, serious emotional distress, and other harm in an amount to be determined at trial.

77. Defendant's culture media was used as intended when it came into contact with Plaintiffs' and class members' embryos.

Risk-Benefit Test

78. Defendant's culture media's design was a substantial factor in causing Plaintiffs' and class members' damages, including economic loss, serious emotional distress, and other harm in an amount to be determined at trial.

79. In particular, the culture media, which should have promoted the development of human embryos fertilized *in vitro* was defectively designed. Among other things, the culture formulation lacked

a sufficient level of magnesium, causing Plaintiffs' and class members' embryos to stop developing and preventing them from reaching viability.

80. Any benefits to its design that Defendant may allege in answer to this complaint do not outweigh the risks of the design, taking into account the gravity of the potential harm, the likelihood the harm would occur, the feasibility of an alternative design, the cost of an alternative design, and any disadvantage associated with an alternative design.

81. Defendant's culture media was used as intended when it came into contact with Plaintiffs' and class members' embryos.

THIRD CAUSE OF ACTION

Strict Products Liability – Failure to Warn

82. Plaintiffs incorporate the above and below allegations by reference.

83. Defendant designed, manufactured, tested, supplied distributed, and/or sold the defective culture media, including the culture media used on Plaintiffs' and class members' embryos.

84. Defendant's culture media had potential risks—including but not limited to defective formulation due to a lack of magnesium—that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community at the time of the manufacture, distribution, or sale of the culture media.

85. Defendant's culture media was defective and unreasonably dangerous when it left Defendant's possession because it did not contain adequate warnings, including warnings concerning the risk of defect that its formulation lacked sufficient magnesium and would stop embryos development.

86. The potential risks of destroying and preventing the development of human embryos upon contact presented a substantial danger when Defendant's culture media was used or misused in an intended or reasonably foreseeable way.

87. The ordinary consumer would not have recognized the potential for risks. Defendant knew or reasonably should have known that users may not have adequate quality control measures in place to detect the dangers of the culture media before applying it to reproductive cells, and failed to adequately warn or instruct concerning the potential risks of applying the culture media to reproductive cells when a

reasonable manufacturer, distributor, or seller under similar circumstances would have warned of the danger or instructed in the safe use of the culture media.

88. Defendant had constructive notice or knowledge and knew, or in the exercise of reasonable care should have known, that the culture media was dangerous, had risks, was defective in manufacture or design, including that it would destroy and prevent the development of human embryos upon contact.

89. Defendant failed to adequately warn or instruct of the potential risks of applying its defective culture media to human reproductive material.

90. It was foreseeable to Defendant that failure to adequately warn about the risks of its culture media would cause irreparable harm to those whose embryos were exposed to it during IVF, including the types of emotional distress suffered by Plaintiffs and class members.

91. As a result of Defendant's failures to adequately warn, Plaintiffs and class members were harmed as described herein. Defendant's failure to warn was a substantial factor in causing Plaintiffs' and class members' damages, including economic loss, serious emotional distress, and other harm in an amount to be determined at trial.

92. Defendant's culture media was used as intended when it came into contact with Plaintiffs' and class members' embryos.

FOURTH CAUSE OF ACTION

Negligent Failure to Recall

93. Plaintiffs incorporate the above and below allegations by reference.

94. Defendant designed, manufactured, tested, supplied distributed, and/or sold the defective culture media, including the culture media used on Plaintiffs' and class members' embryos.

95. Defendant acted negligently by failing to recall its defective culture media products, prior to its use in the IVF process for Plaintiffs' and class members' embryos.

96. Defendant knew or reasonably should have known that, when used as intended, the culture media presented or was likely to present a danger to developing human embryos, including that it would destroy and prevent the development of human embryos upon contact.

97. After Defendant sold the defective culture media to Plaintiffs' and class members' fertility clinics and before the defective culture media was used on Plaintiffs' and class members' embryos, Defendant knew or reasonably should have known that the culture media was insufficiently tested, monitored, and developed, and that it presented a danger to developing human embryos, including that it would destroy and prevent the development of human embryos upon contact. Nevertheless, at no point during this time period did Defendant recall, repair, or warn of the danger posed by the defective culture media.

98. A reasonable manufacturer, distributor, or seller facing the same or similar circumstances as Defendant would have recalled the defective culture media to ensure developing human embryos were not endangered.

99. Defendant's failure to timely recall the defective culture media was a substantial factor in causing harm to Plaintiffs and class members. Had Defendant recalled the defective culture media before it was used on Plaintiffs' and class members' embryos, its fertility clinics would not have used it, and it would not have destroyed, damaged, or prevented the development of Plaintiffs' and class members' embryos upon contact.

FIFTH CAUSE OF ACTION

Negligence/Gross Negligence

100. Plaintiffs incorporate the above and below allegations by reference.

101. Defendant owed Plaintiffs and class members a duty to exercise the highest degree of care when it designed, produced, manufactured, assembled, sold, supplied and/or otherwise placed the defective culture media into the stream of commerce for use in the growth and development of human embryos.

102. Defendant knew or reasonably should have known that its culture media needed to be designed, produced, manufactured, assembled, maintained, inspected, sold and supplied properly, without defects and with due care, for safe use in the growth and development of human embryos. Defendant was negligent, reckless, and careless and failed to take the care and duty owed to Plaintiffs and class members, thereby causing Plaintiffs and class members to suffer harm.

103. Defendant breached this duty and was negligent in the design, manufacture, inspection, and/or testing of its embryo culture media, and produced an unsafe, dangerous, and defective embryo culture media that guaranteed the failure of embryotic viability during the IVF process.

104. Defendant could have reasonably foreseen that if Defendant's embryo culture media was defective, consumers of the embryo culture media, like Plaintiffs, would have experienced economic loss and serious emotional distress as a result of Defendant's breach of its duty of care.

105. As a direct and proximate result of Defendant's negligent acts and/or omissions, including but not limited to, failing to properly or adequately test its embryo culture media, promoting and marketing its embryo culture media as properly tested and safe for use on human embryos despite its knowledge of its defective nature, defectively designing its embryo culture media, defectively manufacturing its embryo culture media, and/or failing to adequately warn of the dangerous effects of the culture media, Plaintiffs and class members were harmed as described herein, including the destruction of their developing embryos.

106. These negligent acts and/or omissions were a substantial factor in causing Plaintiffs' and class members' damages, including economic loss, serious emotional distress, and other harm in an amount to be determined at trial.

107. Imposing a duty on Defendant to avoid causing emotional distress would promote the policy of preventing future harm, insofar as it will be motivated to take steps to ensure that its embryo culture media products are free from defects capable of destroying, damaging, or jeopardizing the embryos they are designed to help develop. Imposing a duty on Defendant to avoid causing emotional distress also furthers the community's interest in ensuring that reliable fertility services are available to those who wish to become parents.

108. The burden on Defendant from a duty to avoid causing emotional distress is fair and appropriate, in light of the importance of the embryos it voluntarily agreed to protect, at considerable cost to Plaintiffs and class members.

109. Defendant's acts and omissions constitute gross negligence because they are an extreme departure from what a reasonably careful person would do in the same situation to prevent foreseeable loss of embryos during the IVF process.

110. Defendant acted willfully, wantonly, and with a conscious disregard for the safety of consumers and/or users of its embryo culture media, including Plaintiffs, because Defendant was aware of the dangerous consequences of not properly or adequately testing its embryo culture media, Defendant knew or should have known the embryo culture media lacked vital nutrients such that it posted a severe risk to irreplaceable developing human embryos, and failed to recall the culture media before it was used to culture and develop Plaintiffs' and class members' embryos.

SIXTH CAUSE OF ACTION

Trespass to Chattels

111. Plaintiffs incorporate the above and below allegations by reference.

112. Plaintiffs and class members owned or had the right to possess their reproductive material—their developing embryos—that was destroyed by Defendant's embryo culture media.

113. Defendant intentionally interfered with Plaintiffs' and class members' possession of their developing embryos by manufacturing a defective product that destroyed the material instead of safely culturing the fertilized eggs to develop into healthy embryos, and by failing to recall or warn about the dangers of this product before it was used on Plaintiffs' and class members' reproductive material.

114. Plaintiffs and class members did not consent to or authorize the use of a faulty and defective culture media on their developing embryos.

115. Defendant caused physical damage to Plaintiffs' and class members' personal property when the defective culture media destroyed their developing embryos.

116. Defendant impaired the condition, quality, or value of Plaintiffs' and class members' personal property when the defective culture media prevented the developing embryos from becoming viable.

117. Defendant's interference with Plaintiffs' and class members' reproductive material proximately caused harm to Plaintiffs and class members, as described herein, including by destroying their embryos.

118. As a foreseeable, direct and proximate result of the harm to Plaintiffs' and class members' reproductive material caused by Defendant's trespass, Plaintiffs and class members have suffered and continue to suffer injuries in an amount to be determined at trial, including economic loss, serious

emotional distress, and other harm in an amount to be determined at trial. A reasonable person in Plaintiffs' and class members' position would sustain emotional distress as a result of Defendant's conduct described herein.

SEVENTH CAUSE OF ACTION

Unjust Enrichment

119. Plaintiffs incorporate the above allegations by reference.

120. Plaintiffs and class members conferred a tangible and material economic benefit on Defendant by purchasing the defective culture media.

121. Defendant voluntarily and readily accepted and retained the benefits.

122. Plaintiffs and class members would not have purchased the culture media had they known its defective nature.

123. This benefit was obtained unlawfully. Defendant marketed its embryo culture media as being safe and effective for use on Plaintiffs' and class members' reproductive material. Defendant knew or should have known that the payments rendered by Plaintiffs and class members were given with the expectation that the embryo culture media would have the qualities, characteristics, and suitability for use represented by Defendant.

124. Defendant received benefits in the form of revenues from purchases of its culture media to the detriment of Plaintiffs and class members, who purchased defective embryo culture media that was not what Plaintiffs and class members bargained for and was not safe and effective, as claimed by Defendant.

125. It would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

126. Defendant has been unjustly enriched in retaining the benefits derived from the purchase of defective culture media by Plaintiffs and class members. Retention of the payments received under these circumstances is unjust and inequitable because Defendant's representations and labeling of the recalled embryo culture media lots was misleading to consumers, which caused injuries to Plaintiffs and class members because they would have not purchased the culture media had they known its true, defective nature.

127. Plaintiffs and class members are entitled to restitution and to recover from Defendant all amounts wrongfully and improperly retained in the amount necessary to Plaintiffs and class members to the position they occupied prior to purchasing and being harmed by the defective culture media.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the class defined above, respectfully request that the Court:

a. Certify this action as a class action under Rule 23 of the Federal Rules of Civil Procedure, appoint Plaintiffs as class representatives, and appoint the undersigned counsel as class counsel;

b. Award Plaintiffs and class members compensatory, restitutionary, punitive, and/or exemplary damages in an amount to be determined at trial;

c. Award prejudgment interest as permitted by law;

d. Award reasonable attorneys' fees and costs, as permitted for by law; and

e. Grant such other and further relief as the Court deems equitable, just, or proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: January 21, 2025

Respectfully submitted,

/s/ *Dena C. Sharp*

Dena C. Sharp (State Bar No. 245869)
Adam E. Polk (State Bar No. 273000)
Nina R. Gliozzo (State Bar No. 333569)
Patrick T. Johnson (State bar No. 329580)
GIRARD SHARP LLP
601 California Street, Suite 1400
San Francisco, CA 94108
Telephone: (415) 981-4800
Email: dsharp@girardsharp.com
Email: apolk@girardsharp.com
Email: ngliozzo@girardsharp.com
Email: pjohnson@girardsharp.com

Joseph G. Sauder
Matthew D. Schelkopf

Juliette T. Mogenson
SAUDER SCHELKOPF LLC
1109 Lancaster Avenue
Berwyn, PA 19312
Tel: (888) 711-9975
Facsimile: (610) 421-1326
Email: jgs@sstriallawyers.com
Email: mds@sstriallawyers.com
Email: jtm@sstriallawyers.com

Tracey B. Cowan (State Bar No. 250053)
CLARKSON LAW FIRM, P.C.
95 3rd St., 2nd Floor
San Francisco, CA 94103
Telephone: (213) 788-4050
Facsimile: (213) 788-4070
Email: tcowan@clarksonlawfirm.com

Ryan J. Clarkson (State Bar No. 257074)
Shireen M. Clarkson (State Bar No. 237882)
Olivia E. Davis (State Bar No. 353041)
CLARKSON LAW FIRM, P.C.
22525 Pacific Coast Highway
Malibu, CA 90265
Telephone: (213) 788-4050
Facsimile: (213) 788-4070
Email: rclarkson@clarksonlawfirm.com
Email: sclarkson@clarksonlawfirm.com
Email: odavis@clarksonlawfirm.com

Counsel for Plaintiffs and the Proposed Class